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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/037,807      | 12/26/2001  | Michael S. H. Chu    | 81745               | 6255             |

23685 7590 03/14/2005

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EXAMINER

KENNEDY, SHARON E

ART UNIT PAPER NUMBER

3762

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                      |                                   |  |
|------------------------------|--------------------------------------|-----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/037,807 | <b>Applicant(s)</b><br>CHU ET AL. |  |
|                              | <b>Examiner</b><br>Sharon Kennedy    | <b>Art Unit</b><br>3762           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) 4, 12, 16, 29, 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-11, 13-15, 17-28, 30, 34-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

#### ***Claim Rejections - 35 USC § 102***

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bonaldo, US 5,947,954. See the figure on the front page of the patent.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Steer, US 4,603,837. See especially figure 4. The claimed tube is anticipated by first tube 110; the claimed tube support is anticipated by pipe 115.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by French et al., US 6,095,997. French discloses the tube support 20, tube 50 and means 40 for securing to a medical catheter. Although the French device is used for a different purpose, nothing in the claims structurally distinguishes over French.

#### ***Claim Rejections - 35 USC § 103***

Claims 1-3, 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelliher '924 in view of Delegge '901. As stated in the previous office action, it is well settled that making a device integral or separable is *prima facie* obvious in the lack of a showing of criticality. See MPEP 2144.04 V. C., entitled, "Making Separable." The only difference between Kelliher and the claimed device is that the Kelliher balloon catheter is integral with the external retention portion 189. Applicant's

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catheter is separable, and uses a common connector to attach the pieces. Applicant's specification has not set forth any unusual effect resulting from making the parts separable; accordingly, these claims must be rejected.

Claims 5-10, 17-24, 27, 28, 30, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelliher '924 in view of Dennehey et al., US 4,417,890. The only difference between Kelliher and the claimed invention is that applicant now claims that the front end of the stem is enclosed in the housing. In other words, the shape of the housing 17 is such that it encloses the connection of the stem. It is well established that changes in shape or size are *prima facie* obvious in the lack of a showing of criticality. See MPEP 2144.04, IV. B., entitled, "Changes in Shape." Applicant's specification does not assert any unusual feature resulting from the expanding the housing so that it encloses the front end of the stem, accordingly, these claims must be rejected. Dennehey is cited to exemplify that recessing a medical connector element within a housing is generally known in the art and useful to achieve a stated purpose (having a cap) if desired. In the alternative, a connection element can be extended out of a housing so that it can be cleaned easier, for example. Each design (Kelliher and applicant's) is different, and each has benefits and drawbacks that are well known in the art and expected.

Claims 11, 13-15, 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelliher '924 and Dennehey '890 as applied to claim 10 above, and

further in view of Delegge, '901. Kelliher and Dennehey disclose all of the claimed embodiments except for the ring-shaped member to secure the medical catheter. Kelliher discloses a one-piece bolster/valve apparatus with the bolster (Kelliher balloon 48) integrally connected to the valve 12. Applicant calls for a two-piece apparatus using a ring-shaped member to connect the bolster. Delegge exemplifies that ring-shaped securing members are well known in two-piece apparatuses. Accordingly, it would be obvious to one of ordinary skill in the art to attach a ring shaped member to make the Kelliher apparatus separable instead of integral. Regarding the claimed step increases for the outer diameter of the lower portion, it appears that Delegge discloses these features for optimally attaching the ring securement device.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelliher '924 and Dennehey '890 as applied to claim 5 above, and further in view of Shmulewitz et al., US 6,569,145. Kelliher and Dennehey disclose all of the claimed embodiments except for the window 53 to permit viewing of the valve position. Shmulewitz discloses that it is known to use a window 60 to show the position of a valve structure. See figures 5A, 5B, and column 7, line 8 of Shmulewitz. Accordingly, it would be obvious to one of ordinary skill in the art to attach a window to the Kelliher apparatus so that it would be visually apparent if the valve were open or closed as shown by Shmulewitz, for the purpose of confirming the valve position.

***Conclusion***


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571/272-4955.

  
Sharon Kennedy  
Primary Examiner  
Art Unit 3762

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